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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/831,656	09/02/2001	Jack Bech Nielsen	5753.204-US	7015
25908	7590	11/14/2003		
NOVOZYMES NORTH AMERICA, INC. 500 FIFTH AVENUE SUITE 1600 NEW YORK, NY 10110			EXAMINER KALLIS, RUSSELL	
			ART UNIT	PAPER NUMBER
			1638	

DATE MAILED: 11/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/831,656

Applicant(s)

NIELSEN ET AL.

Examiner

Russell Kallis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 August 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23-42 is/are pending in the application.
- 4a) Of the above claim(s) 38-42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

The restriction is maintained in view of Applicant's non-traversal. Applicant's assertions of mistaken identity of the alpha amylase are not persuasive. The Vickers reference teaches that plant transformation with some type of amylase gene possessing some kind of maltogenic properties was known and that Applicant's teachings are not an advance over the prior art. The rejection of Claims 23-37 under 35 U.S.C. 103(a) as being unpatentable over Pen J., WO 91/14772 published October 3, 1991 in view of Barro F. *et al.*, Nature Biotechnology, November 1997; Vol. 15; pp. 1295-1299 and in further view of Accession number P19531 submitted February 1, 1991, Diderichsen *et al.* and Christophersen *et al.* reinforces this point of view.

. The rejection of Claims 25-26, 30, 33 and 36 under 35 U.S.C. 112, second paragraph is withdrawn in view of Applicant's amendments and arguments.

The rejection of Claims 23-24 and 28 under 35 U.S.C. 102(b) as being anticipated by Van Ooyen *et al.*, U.S. Patent 5,705,375 issued January 6, 1998 in light of Vickers *et al.* 1995 I is withdrawn in view of Applicant's arguments.

The rejection of Claims 23-24, 27-28, 30-32, 34-35, and 37 under 35 U.S.C. 103(a) as being unpatentable over Pen J., WO 91/14772 published October 3, 1991 in view of Barro F. *et al.*, Nature Biotechnology, November 1997; Vol. 15; pp. 1295-1299 are withdrawn in view of Applicant's arguments.

Claim Rejections - 35 USC § 112

Claims 23-37 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is maintained for the reasons of record set forth in the Official action mailed 4/11/2003. Applicant's arguments filed 8/19/2003 have been considered but are not deemed persuasive.

Applicant's assertion that numerous maltogenic alpha amylases are described in the specification that have at least 70% sequence identity to SEQ ID NO: 2 is not supported by the teachings of the specification and are speculative in nature (response pages 6-7). Nowhere in the cited passages of the specification does Applicant provide any one to one comparisons of the broadly claimed and non-exemplified genus of amino acid sequences having maltogenic activity and at least 70% sequence identity to SEQ ID NO: 2.

Applicants assert that many of the variants described in U.S. Patent 6,162,628 were in fact made (response page 7). The variants described in the '628 Patent are variants based upon one exemplified maltogenic alpha amylase protein sequence from a single bacterial sequence and as argued above there is no one to one comparisons of the sequences of the '628 Patent or the variants of the instant specification to SEQ ID NO: 2. In addition, Applicant provides no guidance as to which combinations of the vast myriad of amino acid substitutions cited in the specification would recover maltogenic alpha amylase activity.

Further, the '628 Patent deals with variations over the entire range of the amino acid sequence while the instant Application only claims a range covering amino acids 34 to 719 of

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SEQ ID NO: 2. Furthermore, the '628 Patent deals with proteins while the claims of the instant Application are drawn to the genes encoding proteins. Moreover, the '628 Patent does not provide conserved sequences of the genes which are correlated with function, as per MPEP 2163 and Written Description Guidelines.

The '^{patent}628 is insufficient to support the written description or enablement of the instant claims. The instant specification and the prior art should provide enabling disclosure. See *Genentech, Inc. v. Novo Nordisk, A/S*, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that disclosure of a "mere germ of an idea does not constitute [an] enabling disclosure", and that "the specification, not the knowledge of one skilled in the art" must supply the enabling aspects of the invention.

Claims 23-37 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is maintained for the reasons of record set forth in the Official action mailed 4/11/2003. Applicant's arguments filed 8/19/2003 have been considered but are not deemed persuasive.

Applicant asserts that the claims are directed to transgenic cereal cells not sequences and since the broadly claimed variants can be made without undue experimentation the transgenic cells and plants of the invention are enabled (response pages 7-8). Since Applicant has not described the claimed sequences of the invention as argued supra, Applicant has not taught how to make the broadly claimed sequences of the invention and the host cells and plants therewith.

Applicant's assertion that the Sweetlove experiments involving overexpression of ADP glucose pyrophosphorylase have no bearing upon Applicant's ability to make transgenic cells and plants is acknowledged (response page 10, lines 3-10). However, Applicants has also claimed an amount of maltogenic alpha amylase effective to delay staling of baked bread, requiring that the claimed variants have maltogenic activity in a plant, ^{just their} and not mere presence. This argument is supported by Applicant's assertion that ^{the} amount of enzyme may have relevance to the application of the transgenic plants (see response page 10, lines 5-7).

Applicant further asserts that the amount of experimentation to practice the invention is routinely encountered in the art, and since the nature of the experimentation is only finding suitable materials such as promoters and host cells, the claims are thus enabled (response page 10). The claims are broadly drawn to sequences comprising any number of substitutions covering as much as 30% of the amino acid sequence of SEQ ID NO: 2. Given the lack of teaching of which amino acid substitutions comprising a variant having 70% sequence identity to SEQ ID NO: 2 without any teaching as to which combination of substitutions could be predictably eliminated, one of skill in the art would be required to test a myriad of variants for maltogenic activity of the broadly claimed genus having 70% sequence identity, and thus the claims are not enabled.

Claim Rejections - 35 USC § 103

Claims 23-37 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Pen J., WO 91/14772 published October 3, 1991 in view of Barro F. *et al.*, Nature Biotechnology, November 1997; Vol. 15; pp. 1295-1299 and in further view of Accession number P19531 submitted February 1, 1991, Diderichsen *et al.* and Christophersen *et al.* This rejection is

maintained for the reasons of record set forth in the Official action mailed 4/11/2003.

Applicant's arguments filed 8/19/2003 have been considered but are not deemed persuasive.

Applicant asserts that the enzyme taught by Diderichsen *et al.* has a different activity than that of Pen *et al.* However, it is obvious to incorporate the enzyme taught by Diderichsen *et al.* because the skilled artisan would recognize that it has beneficial properties for baking and therefore it would be obvious to incorporate the maltogenic alpha amylase gene into a cereal plant because both Pen and Barro teach that modification of transgenic cereal plants with genes that modify carbohydrates in a plant are of significant industrial importance. Moreover, Applicant's arguments with respect to non-obviousness are limited only to SEQ ID NO: 1 encoding SEQ ID NO: 2. See *In re Lindner*, 173 USPQ 356 (CCPA 1972) and *In re Grasselli*, 218 USPQ 769 (Fed. Cir. 1983) which teach that the evidence of nonobviousness should be commensurate with the scope of the claims.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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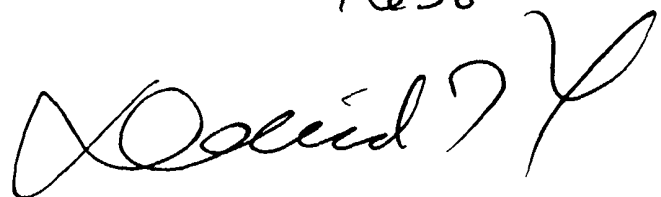
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Kallis whose telephone number is (703) 305-5417. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0198.

Russell Kallis Ph.D.
October 29, 2003

DAVID T. FOX
PRIMARY EXAMINER
GROUP ~~180~~ 1638

A handwritten signature in black ink, appearing to read "David T. Fox", with a large, stylized flourish at the end.